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UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/605,573 06/28/00 DE LEYS

R CDS-222

EXAMINER

HM12/1003

AUDLEY A CIAMPORCERO JR ESQ
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NEW BRUNSWICK NJ 08933-7003

PARKIN, J

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/605,573

Applicant(s)
De Leys, R. And J. Zheng

Examiner
Jeffrey S. Parkin, Ph.D.

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 28 Jun 2000

2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-15 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-3, 5, drawn to a single HIV-1 **peptide**, classified in class 530, subclasses 300, 324, 325, and 326.
- b. Group II, claim(s) 4, drawn to an **antibody** directed against a single HIV-1 **peptide**, classified in class 530, subclass 387.9.
- c. Group III, claim(s) 6-8, drawn to a **nucleic acid** encoding a single HIV-1 **peptide**, classified in class 536, subclass 23.72.
- d. Group IV, claim(s) 9, drawn to a **method** for the **production** of a single HIV-1 **peptide**, classified in class 435, subclass 69.1.
- e. Group V, claim(s) 10, drawn to a **test kit** comprising a single HIV-1 **peptide**, classified in class 422, subclass 61.
- f. Group VI, claim(s) 11, drawn to an **in vitro diagnostic assay** **employing** a single HIV-1 **peptide**, classified in class 435, subclass 7.1.
- g. Group VII, claim(s) 12, drawn to an **in vitro diagnostic assay** **employing** a single **antibody** to an HIV-1 **peptide**, classified in class 435, subclass 5.
- h. Group VIII, claim(s) 13-15, drawn to a single **HIV-1 mosaic peptide**, classified in class 530, subclasses 300 and 350.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-III, V, and VIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified groups is directed toward a structurally different product or composition with different attendant immunological, biochemical, and physical activities. Separate searches will also

be required for each group. Therefore, each invention is clearly drawn toward a different inventive entity.

5 4. Inventions IV, VI, and VII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the identified methods is directed toward a different scientific
10 objective (e.g., protein production, antibody capture assay, antigen capture assay) that employs materially different reagents and protocols. Each group will necessitate a separate search. Accordingly, each invention is clearly drawn toward a different inventive concept.

15 5. Inventions I and VII, II and IV/VI, III and VI/VII, V and IV/VI/VII, and VIII and IV/VI/VII, respectively, are each unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have
20 different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, none of the products identified in Groups I, II, III, V, and VIII are required to practice the methodologies of the corresponding groups, and the corresponding
25 groups neither require nor use their respective peptides. Therefore, each invention is clearly drawn toward a different inventive entity.

30 6. Inventions I and VI, II and VII, and III and IV, respectively, are each related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (M.P.E.P. ¶ 806.05(h)). In the instant case, each of the products identified can be employed in materially different processes. For instance, the peptide of Group I can be utilized as an immunogen to produce immunological reagents, the antibody of Group II can be utilized in affinity purification procedures, and the nucleic acids of Group III can be utilized as probes for the detection of virus.

7. Inventions I and IV are related as product made and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different products, or (2) the product as claimed can be made by another and materially different process (M.P.E.P. ¶ 806.05(f)). In the instant case, the peptide of Group I can be prepared by a materially different process such as solid-state peptide synthesis.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, requirement for independent searches, and recognized divergent subject matter, restriction for examination purposes as indicated is proper. Applicants are required under 35 U.S.C. § 121 to elect a single group for prosecution on the merits. Applicants are further advised that a single peptide should also be elected where appropriate. Because of their unique amino acid sequence, each peptide constitutes an independent and distinct invention. Separate searches will be required for each peptide. Applicants are also reminded that the claims should be amended, if necessary, to reflect the election.

Claim Cancellation

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

10. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

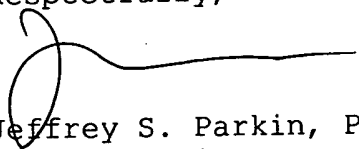
11. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

12. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122,

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Applicants: De Leys, R. and J. Zheng

respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2001